

SECTION L – INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

The following information is specific to this solicitation and is provided to supplement and/or complete the associated ITEMS presented at the SECTION L website at <http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf>.

I. General Information

Item 2: Alternate I, of FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISITION, is applicable to this solicitation.

Item 9: NAICS CODE AND SIZE STANDARD:

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- (1) The NAICS Code is 493190.
- (2) The small business size standard is \$21,500,000 in annual receipts.

Item 10: THIS REQUIREMENT IS NOT SET ASIDE FOR SMALL BUSINESS is applicable to this solicitation.

Item 11: TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that one award will be made for this solicitation and that the award will be made on or about December 1, 2005.

It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Period of Performance of three (3) years with four (4) additional years possible under the award term provisions. Incremental funding will be used. See Section L, PART IV-Business Proposal Instructions.

Item 13: ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 23,920 labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

Item 16: COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

Item 17: REFERENCE MATERIALS are available as follows:

PLACE:	Room 6071 6120 Executive Blvd. Rockville, Maryland
DATES AVAILABLE:	April 19, 2005 through May 12, 2005, excluding weekends and Federal Holidays.
TIMES AVAILABLE:	10:00AM - 3:00PM (Local Time)
CONTACT FOR APPOINTMENT:	Bophany Koy Procurement Technician, TBSS, RCB 301-435-3816 koyb@mail.nih.gov

AWARD TERM PROCEDURES are applicable to any contract resulting from this solicitation. The following Exhibits include the specifics of the Award Term Procedures.

[EXHIBIT 1 - Award Term Procedures/Quality Assurance Surveillance Plan \(QASP\)](#)
[EXHIBIT 2 - Contractor Assessment Report](#)
[EXHIBIT 3 - Contractor Assessment Report Performance Indicators and Standards](#)

PLEASE NOTE: The deadline for receipt of all questions related to this solicitation is May 13, 2005, by 3:30PM (Local Time); please send all questions electronically (by email) to the Contract Specialist, John R. Manouelian, at manouelj@mail.nih.gov.

II. General Instructions

Item 23: Potential Award Without Discussions is applicable to this solicitation.

Item 33: Small Business Subcontracting Plan is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

The anticipated minimum subcontracting goals for this RFP are as follows:

20% for Small Business; 3% for Small Disadvantaged Business; 3% for Women-Owned Small Business; 2% for HUBZone Small Business; and 1.5% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

Item 35: Extent of Small Disadvantaged Business Participation is applicable to this solicitation.

Item 39: Past Performance Information is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

Past Performance information shall be submitted as part of the Business proposal.

Proposals should include a list of the last three contracts completed during the past three years and all contracts currently in process that are similar in nature to the solicitation workscope.

Item 49: Solicitation Provisions Incorporated by Reference: The following provisions are applicable to this solicitation.

Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).

Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).

Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

Facsimile Proposals, FAR Clause 52.215-5, (October 1997).

Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity for Construction, FAR 52.222-23, (February 1999).

Preparation of Proposals-Construction, FAR Clause 52.236-28, (October 1997).

Identification of Uncompensated Overtime, FAR Clause 52.237-10, (October 1997).

III. Technical Proposal Instructions

Item 54: Information Technology Systems Security, is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation.

(a) **Sensitivity and Security Level Designations.**

The Statement of Work (SOW) requires the successful offeror to develop or access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the *Department of Health and Human Services (DHHS) Security Program Policy*, the Government has determined that the following apply:

(1) Category of Safeguarded Information

The safeguarded agency information that the successful offeror will develop or access is categorized as:

- ☒ Non Sensitive Information
☐ Sensitive Information

Contracts that will require hosting of government data, web sites, applications or domain names will be required to provide regular vulnerability assessments and remediation reports to the ISSO and PO. The frequency of these reports will be monthly unless otherwise noted or negotiated.

(2) Security Level Designations

The information that the successful offeror will develop or access is designated as follows:

- Level 1** applies to the sensitivity of the data.
Level 1 applies to the operational criticality of the data.
The overall Security Level designation for this requirement is **Level ____**.

(3) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following designations apply:

- ☐ **Level 6C: Sensitive - High Risk (Requires Suitability Determination with a BI).**
Contractor employees assigned to a Level 6C position are subject to a Background Investigation (BI).
- ☐ **Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI).**
Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit

Check (NACIC), a Minimum Background Investigation (MBI), or possibly a Limited Background Investigation (LBI).

[X] Level 1C: Non Sensitive (Requires Suitability Determination with an NACI).

Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the contractor will be required to submit a roster of all IT staff working under the contract. The Government will determine the appropriate level of suitability investigation required for each staff member.

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(b) Information Technology (IT) System Security Program

The offeror's proposal must:

- (1) Include a detailed System Security Plan (SSP) of its present and proposed IT systems security program commensurate with the size and complexity of the requirements of the Statement of Work. Offeror's must use the NIH Application/System Security Plan Template available at:

- (i) SSP Template (detailed)
<http://irm.cit.nih.gov/security/secplantemp.doc>
- (ii) Security Plan Outline (outline only)
http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc

The resultant contract will require completion of the SSP no later than 90 days after contract award.

OR

- (1) The offeror's plan shall provide detail commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed shall include, but are not limited to administrative, technical, and physical security as follows:
 - (i) Security Awareness Training
 - (ii) Access Control
 - Network (ex: firewall)
 - System (ex: network OS, tcp wrappers, SSH)
 - Application (ex: S-LDAP, SSL)
 - Remote Access (ex: VPN)
 - Monitoring and support (ex: IDS, pager, NOC)
 - (iii) Protection against data loss
 - OS security (ex: patch management, configuration)
 - Application security (ex: patch management)
 - Database security
 - Back-up and recovery
 - Fault tolerance, high availability
 - (iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
 - (v) Physical Security
 - Access control (ex: locks, guards)
 - Power conditioning and/or UPS
 - Air conditioning
 - Fire protection
- (2) Demonstrate that it complies with the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS Security Program Policy.
- (3) Include an acknowledgment of its understanding of the security requirements.
- (4) Provide similar information for any proposed subcontractor developing or accessing an AIS.

(c) **Required Training for IT Systems Security**

DHHS policy requires that contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the following NIH Computer Security Awareness Training course prior to performing any contract work: <http://irtsectraining.nih.gov/>. The contractor will be required to maintain a listing of all individuals who have completed this training and submit this listing to the Government.

Additional security training requirements commensurate with the position may be required as defined in OMB Circular A-130 or NIST Special Publication 800-16, "Information Technology Security Training Requirements." These documents provide information about IT security training that may be useful to potential offerors.

(d) **Prospective Offeror Non-Disclosure Agreement**

The Government has determined that prospective offerors will require access to sensitive information described below in order to prepare an offer.

Any individual having access to this information must possess a valid and current suitability determination at the following level:

- ☐ **Level 6C: Sensitive - High Risk**
- ☐ **Level 5C: Sensitive - Moderate Risk**

To be considered for access to this sensitive information, a prospective offeror must:

- (1) Submit a written request to the Contracting Officer identified in the solicitation;
- (2) Complete and submit the "Prospective Offeror Non-Disclosure Agreement" provided as an attachment in Section J of this solicitation; and
- (3) Receive written approval from the Contracting Officer.

Prospective offerors are required to process their requests for access, receive Government approval, and then access the sensitive information within the period of time provided in the solicitation for the preparation of offers.

Nothing in this provision shall be construed, in any manner, by a prospective offeror as an extension to the stated date, time, and location in the solicitation for the submission of offers.

(e) **References**

The following documents are electronically accessible:

- (1) OMB Circular A-130, Appendix III:
http://www.whitehouse.gov/omb/circulars/a130/a130appendix_iii.html
- (2) DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
- (3) NIH Applications/Systems Security Template: <http://irm.cit.nih.gov/security/secplantemp.doc>
- (4) NIH Security Plan Outline: http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
- (5) NIST Special Publication 800-16, "Information Technology Security Training Requirements:"
<http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>
Appendix A-D: <http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf>
- (6) NIH CIT-Policies, Guidelines and Regulations:
Table 1 - Categories of Safeguarded Agency Information:
<http://irm.cit.nih.gov/security/table1.htm>
Table 2 - Security Level Designations for Agency Information:
<http://irm.cit.nih.gov/security/table2.htm>
Table 3 - Positions Sensitivity Designations for Individuals Accessing Agency Information:
<http://irm.cit.nih.gov/security/table3.htm>
- (7) NCI Information Technology Security Policies, Forms and Procedures for Contracts:
<http://ais.nci.nih.gov/>

The technical discussion included in the technical proposal should respond to the items set forth below:

A. Staff Capabilities and Qualifications

i. General:

Describe the experience and qualifications of personnel who will be assigned for direct work on this project. Information is required that will show the composition of the work group, its general qualifications, and recent experience with similar projects. Because of the diversity of tasks to be performed, each area of the Statement of Work should be addressed in sufficient detail to permit evaluation of the proposal in terms of the adequacy and availability, as needed, of all staff to be assigned to the project. Indicate the approximate percentage of total time each could be made available for this contract and specifically to which tasks each employee would be assigned. Also demonstrate that Contractor employees will be available on short notice, and under conditions of multiple and competing tasks. For any proposed personnel who are not assigned 100% of their time to this project, describe how you can assure their availability when needed.

Within the estimated level of effort, offerors should indicate the specific level of effort that they consider appropriate for each function outlined in the Statement of Work. Provide a Personnel Ranking Matrix that indicates the hierarchical line of supervisory authority, and indicate which contractor employee(s) will perform the various tasks.

Provide complete, detailed resumes of the Principal Investigator and all other senior level personnel that will indicate their educational background, recent relevant experience, and professional accomplishments. Include dates, places, and names of previous employers, and any related training. State the estimated time to be spent on the project. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment is required; a resume does not meet this requirement.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

iii. Personnel Qualifications:

The Contractor should provide a team with the following qualifications:

a. Principal Investigator (key person)

List the name of the Principal Investigator responsible for overall implementation of the contract and who will serve as the offeror's key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator who will be responsible for the overall implementation of any awarded contract. It is recommended that the Principal Investigator have experience in the following areas; supervisory personnel management, Good Manufacturing Practices (GMP's), warehouse management of pharmaceuticals, and those areas described in the work scope. Discuss the qualifications, experience, and accomplishments of the Principal Investigator. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible. The Principal Investigator shall be an employee of the offeror and not a consultant or subcontractor. It is recommended one person be assigned 100% to this project.

b. Pharmacist Manager, Blinded Dispensing; Assistant P.I. (key position)

This member of the proposed project team shall be trained, qualified, and licensed as a Pharmacist in the state (or District of Columbia) in which the repository is located. It is desirable that the Pharmacist have experience with dispensing and record keeping of investigational agents, as well as familiarity with strategies for packaging and labeling for agents used in blinded clinical trials. It is recommended one person be assigned 100% to this project. This individual will be trained to cover the duties of the P.I.

c. Staff Pharmacists/Blinded Dispensing

Additional pharmacist time is recommended to fill the requirement for pharmacist checking of blinded dispensing of study agents. This person or persons shall also be trained, qualified, and licensed as a Pharmacist in the state (or District of Columbia) in which the repository is located, and should be trained to cover for the Pharmacist Manager in his/her absence and to provide a second check for open label shipments as necessary.

d. Pharmacy Technicians/Blinded Dispensing

Training and/or experience as a pharmacy technician in a hospital or community pharmacy is recommended. It is recommended that two persons be assigned 100% to this project.

e. Warehouse Manager; Assistant P.I. (key position)

The Contractor must designate one person to manage warehouse operations including receipt of incoming shipments, packaging and shipping of agents, auxiliary labeling, and general supervision of repository technicians. It is recommended that one person be assigned 100% to this project. This individual will be trained to cover the duties of the P.I.

f. Repository Technicians

The Contractor must provide adequate staff to package, store, and ship orders for investigational agents, provide supplemental labeling, and perform other warehouse operations. One Repository Technician should be designated to be specifically responsible for the receipt, documentation, and disposal of unused drugs returned from clinical sites. Experience with pharmaceutical warehousing operations would be helpful.

g. Other Support Personnel:

The Contractor must supply support staff to perform the following tasks: clerical and administrative functions; entry of agent receipt and shipment data into a computerized data base; and computer generation of required reports and queries. Discuss their qualifications and experience. State the estimated time each will spend on the project and the functions for which each will be responsible.

B. Understanding of the Project and Proposed Approach

The proposal should include: (1) a statement of the overall objectives of the project, as envisioned by the offeror; and (2) an outline of the technical approach that would be used to achieve the objectives.

The proposal should address each area of the Statement of Work in a manner that describes the offeror's approach to the particular task and methods of quality control for the various tasks. The offeror should demonstrate a clear understanding of FDA regulations, Pharmaceutical Management Branch procedures, and the needs and mission of the Cancer Therapy Evaluation Program. The offeror should also demonstrate an understanding of the potential problems involved with this project.

Include the following specific points in your discussion:

- i. Describe your awareness and understanding of problems involved with shipping, receiving, storage, distribution, disposition, and record keeping for pharmaceuticals, biologicals, and perishable and hazardous substances. Discuss proposed approaches to the resolution of such problems.
- ii. Discuss potential problems and issues involved in packaging and labeling investigational medications in order to meet the requirements for materials used in blinded clinical trials. These studies may require lengthy intervention periods (i.e. years). Describe accountability and quality control measures to assure that labeling is performed correctly.
- iii. Describe proposed security arrangements to protect inventory.
- iv. Describe in detail your approach to packaging and shipping to ensure the safe, intact, timely arrival of the contents of each package shipped. Discuss how to avoid inadvertent contamination of individuals in the event breakage should accidentally occur while a shipment is in transit.
- v. Describe how the transportation requirements of this contract will be met.

- vi. Discuss in detail the approach to processing and packaging returned agents to ensure safe storage, handling, and transportation of the toxic waste products.
- vii. This Contractor will be requested to ship investigational agents under controlled storage conditions (cold packs, dry ice) to countries throughout the world. In some clinical emergencies, the agent must arrive in the minimum possible time. Shipping companies have a variety of restrictions and service limitations to certain countries, and these guidelines change frequently. Similarly, the Customs departments of some countries have unique paperwork requirements in order to accept shipments. Discuss your approach to international shipping of investigational agents in order to minimize transit time and expense of shipments, and to assure that agents arrive at their destination in good condition. As specific examples, please discuss the potential problems, and approaches to solving them, in making the following shipments.
 - (1). 100 x 10 mL vials of frozen drug to Perth, Australia in February.
 - (2) Overnight refrigerated shipment to Montreal, Quebec.
 - (3) Emergency shipment of an agent to Budapest, Hungary on Friday for Saturday delivery.
 - (4) 1 x 1 mL vial of a vaccine product stored at -70°C to Lima, Peru.
 - (5) 3000 x 30 mL vials of an agent classified as a Dangerous Good to South Africa.
 - (6) 40 x 500 mL bottles of an agent to Mexico City, Mexico.
 - (7) Same day delivery of a refrigerated agent to Miami, Florida.
- viii. Please describe your plans for training and replacement of proposed staff throughout the course of the contract and plans for backup coverage of proposed staff when absent due to vacations, medical leave, etc., in order to assure that work scope requirements are completed in an accurate and timely fashion.
- ix. Offerors, other than the incumbent, are required to provide detailed plans and timetable for moving the agent inventory, files, and Government provided equipment from its present location at McKesson BioServices, Inc., 627 Lofstrand Lane, Rockville, MD 20850 to your proposed location. The safe transfer of agent inventory under proper and documented controlled temperature, files, government provided equipment, and the continuity of the daily shipping operation should be addressed in detail. The plan must include, but is not limited to, providing guidelines for the prevention of loss of the collection during shipment, freezer preparation(s), insurance, and how broken supplies will be handled. Additionally, identify any potential problems associated with the move. Consideration should be given to how the Government provided equipment will be moved, how the safe, intact, and timely arrival of agents at the new location while maintaining and documenting adequate controlled temperature storage will be ensured, the desirability of multiple shipments to reduce risk to the collection from accidents, how uninterrupted service will be provided to customers, and any other considerations that the offeror feels are pertinent. Moreover, the cost for the transition and move shall be provided as a separate budget as well as a category in the total estimated budget.

C. Facilities and Equipment

For the purpose of estimating costs, the offeror shall use the following space specifications assumptions.

- i. The current agent inventory occupies:
 - a. 20,000 cubic feet of usable controlled room temperature (15 to 30 degrees Centigrade) storage space.
 - b. 16,415 cubic feet of usable refrigerated (2 to 8 degrees Centigrade) storage space (see Government Furnished Property, Attachment 12).
 - c. 2,980 cubic feet of usable freezer (-20 to -10 degrees Centigrade) storage space (see Government Furnished Property, Attachment 12).
 - d. 240.5 cubic feet of -70 degrees Centigrade usable freezer space (see Government Furnished Property, Attachment 12).

- e. 1,100 linear feet of file space for the storage of documents (see Government Furnished Property, Attachment 12).
- f. 400 square feet for the storage and processing of unused, returned clinical products.

The offeror shall carefully review the Government furnished property list (Attachment 12) and the above information to determine whether the Government Furnished Property alone is sufficient to perform the work.

The facility must comply with all applicable Food and Drug Administration Current Good Manufacturing Practice Guidelines.

ii. Describe the proposed facilities and equipment as follows:

- a. Describe in detail the facility that will be directly utilized and available for this project. Provide a detailed floor plan of the proposed facility including dimensions drawn to scale, and proposed location of equipment. All copies of floor plans must be legible. In addition to the above referenced storage space requirements, sufficient support space (office, packaging and labeling area, records area, toxic waste storage area, etc.) must be provided. Storage areas shall be accessible to a loading dock or alternate facility for receiving and shipping.
- b. If renovation is planned, provide a floor plan of the proposed space as it currently exists. Describe thoroughly any expansion/renovation (current or planned) that may be necessary for fulfillment of the contract requirements. Also, provide a detailed timetable for the accomplishment of such expansion/renovation including a final date on which full operation would begin.
- c. Describe how the proposed facility will be in compliance with the requirements of the FDA Current Good Manufacturing Practice guidelines.
- d. Describe security arrangements available to safeguard the Government-owned agents to prevent theft or misuse.
- e. Describe the systems, procedures, or programs that would be used to document and ensure maintenance of low temperature (freezer and refrigerator) storage conditions in the event of a failure to the primary system.
- f. Describe the proposed fire containment/alarm system and procedures.
- g. Provide the specific location of the proposed facility, including its address.
- h. If any facility or piece of equipment is not under the complete and direct control of the Principal Investigator, describe the arrangements that will be made to ensure its availability to this contract.

D. Organizational Background and Experience

Offerors should describe in detail prior experience of the organization in furnishing services similar to each area described in the Statement of Work. The proposal should include sufficient information to demonstrate the previous effectiveness of the firm in similar or related work. Include documentation with specific reference to applicable contract numbers, dates of agreements, and dollar volume. This documentation should include clear and concise descriptions of these project(s) and should indicate the project sponsor (e.g. pharmaceutical company, government contract, etc.). For each of the described projects, references (including phone numbers) should be provided.

Please note that organizational experience is defined as accomplishment of work, either past or ongoing which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in the RFP.

Please specifically address the following:

- i. Describe in detail organizational activities that would indicate satisfactory experience and capability in the storage and shipping of pharmaceuticals, biologicals, perishable, and hazardous substances.

- ii. Discuss the background and experience of your organization in providing security arrangements to safeguard valuable or sensitive items.
- iii. Provide a plan for maintenance and quality assurance of all equipment that will be used for this contract.
- iv. Discuss in detail your awareness of applicable federal regulations including those promulgated by FDA, OSHA, EPA, DOT, and USDA and your proposed approach to comply with such regulations. Similarly, discuss the requirements of local (e.g. county) and state governments, as well as the state Board of Pharmacy, that pertain to your proposed repository site. Submit three copies of your organization's safety manual.
- v. Provide evidence that your organization holds or intends to apply for the required licenses or permits.
- vi. Provide an organizational chart demonstrating lines of authority as they relate to the management and operation of this project.
- vii. Information should be provided on how the organization would support the Principal Investigator in resolving problems or special situations.
- viii. Information should be provided on a demonstrated safety program for handling toxic materials, including appropriate employee training.
- ix. Describe in detail organizational activities that would indicate satisfactory experience with a program for quality assurance in labeling and distributing both open-label and blinded agents, as well as in assuring proper storage conditions for all inventory.

E. Information to Assist Offerors in Technical and Cost Proposal Preparation

The Government includes the following information for proposal preparation purposes only. Assume:

- i. Two hundred twenty (220) drug shipments per day, five (5) days a week, fifty-two (52) weeks a year (less holidays) will be made to investigators in the United States. An average of two (2) separate line items will appear on each shipment. Approximately two hundred twenty (220) shipments per month will be made to investigators outside the United States. Shipping charges to be paid through the contract funds are currently estimated at \$25,000 per month. (This does not represent the total cost of shipping since some of the shipments are paid for by the recipient.)
- ii. Some shipments will require dry ice. Assume that 70,000 pounds of dry ice will be used per year.
- iii. A minimum of two complete physical inventories will be required per year; inventory of each agent must also be counted and reconciled at least once per month.
- iv. Emergency shipments or receipt of agents on weekends or holidays twelve times per year.
- v. Agents to be destroyed are required to be repacked in fiberboard drums that conforms to all requirements of applicable freight classification for dry or solid articles, e.g., drums marked 1G/Y142/S/+year made. An itemized listing of the contents will be attached to each drum. The packed drums will be picked up by the NIH Chemical Waste Disposal Service approximately once per month. It is estimated that approximately 25 such drums will be prepared every 30 days. Certain agents considered more toxic are placed into smaller plastic pails. In addition, certain biological agents that are not accepted by the NIH Disposal Contractor are designated as Special Medical Waste and are handled by a separate contractor. Approximately 11 boxes of Special Medical Waste must be disposed of per month via this separate mechanism.

No additional or supplemental Technical Proposal Instructions are applicable to this solicitation. See III. TECHNICAL PROPOSAL INSTRUCTION of SECTION L at <http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf> for Technical Proposal Instructions.

IV. Business Proposal Instructions

Item 59: **Cost and Pricing Data** is applicable to this solicitation.

Subparagraph 3. Formats for Submission of Line Item Summaries:

- ☒ [X] The format specified in SECTION L at <http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf> is applicable to this solicitation.
- ☐ [] The following format shall be used in lieu of the one specified in SECTION L at <http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf> : *

*It is noted that the format specified above is also applicable to Alternate I, of FAR Clause 52.215-20, Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data.

Item 60: **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data, FAR Clause 52.215-20**, is applicable to this solicitation.

Item 65: **Incremental Funding** is applicable to this solicitation.